

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

BUZZFEED INC.,)
111 East 18th Street, 13th Floor)
New York, NY 10003)

Plaintiff,)

V.

FOOD AND DRUG ADMINISTRATION,)
10903 New Hampshire Avenue)
Silver Spring, MD 20993)

**U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES,**
200 Independence Ave., SW
Washington, DC 20201

Defendants.)

COMPLAINT

1. Plaintiff BUZZFEED INC. files this Freedom of Information Act suit to force Defendants FOOD AND DRUG ADMINISTRATION and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES to release records related to the drugs Brilinta and Kengreal.

PARTIES

2. Plaintiff BUZZFEED INC. is a member of the media and made the FOIA requests at issue in this case.

3. Defendant U.S. DEPARTMENT OF HEALTH AND HUMANS SERVICES (“DHHS”) is a federal agency subject to the Freedom of Information Act, 5 U.S.C. § 552.

4. Defendant FOOD AND DRUG ADMINISTRATION ("FDA") is a federal agency and component of DHHS and is subject to the Freedom of Information Act, 5 U.S.C. § 552.

JURISDICTION AND VENUE

5. This case is brought under 5 U.S.C. § 552(a)(6)(c)(i) and presents a federal question conferring jurisdiction on this Court.

6. Venue is proper under 5 U.S.C. § 552(a)(4)(B).

DEFENDANTS' DECEMBER 5 FOIA VIOLATION (ONSET-OFFSET)

7. On December 5, 2018, BUZZFEED requested from FDA "records, in electronic format, related to the following two clinical trials: 1. A Study of the Onset and Offset of Antiplatelet Effects Comparing Ticagrelor, Clopidogrel, and Placebo With Aspirin...2. Response to Ticagrelor in Clopidogrel Nonresponders and Responders and Effect of Switching Therapies." The trials supported an application for approval of ticagrelor (brand name Brilinta). A true and correct copy of the request is attached as Exhibit A.

8. On December 10, 2018, FDA acknowledged receipt of the request. A true and correct copy of the acknowledgement is attached as Exhibit B.

9. As of the date this suit was filed, FDA has not provided any further response or produced any records in response to the request.

DEFENDANTS' DECEMBER 5 FOIA VIOLATION (PLATO DEATHS)

10. On December 5, 2018, BUZZFEED requested from FDA "[a]ny dataset containing a record of each individual death in the drug clinical trial titled 'The Study of Platelet Inhibition and Patient Outcomes (PLATO)'" The trial supported an application seeking approval of ticagrelor (brand name Brilinta). A true and correct copy of the request is attached as Exhibit C.

11. On December 10, 2018, FDA acknowledged receipt of the request. A true and correct copy of the acknowledgement is attached as Exhibit D.

12. As of the date this suit was filed, FDA has not provided any further response or produced any records in response to the request.

DEFENDANTS' DECEMBER 27 FOIA VIOLATION

13. On December 27, 2018, BUZZFEED made the following request to the FDA: "This request related to the drug clinical trial titled 'The Study of Platelet Inhibition and Patient Outcomes (PLATO)'...According to page 37 of Dr. Thomas Marciniak's May 14, 2011 review, AstraZeneca provided to the FDA information about 'work orders' related to 'inactivations' or 'soft deletions' of data. BuzzFeed News now requests those same records." The trial supported an application seeking approval of ticagrelor (brand name Brilinta). A true and correct copy of the request is attached as Exhibit E.

14. On January 30, 2019, FDA acknowledged receipt of the request. A true and correct copy of the acknowledgement is attached as Exhibit F.

15. As of the date this suit was filed, FDA has not provided any further response or produced any records in response to the request.

DEFENDANTS' JANUARY 15 FOIA VIOLATION

16. On January 15, 2019, BUZZFEED requested from FDA various records related to the following three drug clinical trials: CHAMPION PLATFORM, CHAMPION PCI, and CHAMPION PHOENIX. The trials supported an application seeking approval of cangrelor (brand name Kengreal). A true and correct copy of the request is attached as Exhibit G.

17. On February 3, 2019, FDA acknowledged receipt of the request. A true and correct copy of the acknowledgement is attached as Exhibit H.

18. As of the date this suit was filed, FDA has not provided any further response or produced any records in response to the request.

COUNT I – VIOLATION OF FOIA – DECEMBER 5 REQUEST (ONSET-OFFSET)

19. The above paragraphs are incorporated herein.
20. Defendants are agencies subject to FOIA.
21. Plaintiff made a FOIA request to Defendants for agency records of Defendants.
22. Defendants have failed to provide a determination with regard to the request.
23. Defendants have failed to produce the requested records promptly.

COUNT II – VIOLATION OF FOIA – DECEMBER 5 REQUEST (PLATO DEATHS)

24. The above paragraphs are incorporated herein.
25. Defendants are agencies subject to FOIA.
26. Plaintiff made a FOIA request to Defendants for agency records of Defendants.
27. Defendants have failed to provide a determination with regard to the request.
28. Defendants have failed to produce the requested records promptly.

COUNT III - VIOLATION OF FOIA - DECEMBER 27 REQUEST

29. The above paragraphs are incorporated herein.
30. Defendants are agencies subject to FOIA.
31. Plaintiff made a FOIA request to Defendants for agency records of Defendants.
32. Defendants have failed to provide a determination with regard to the request.
33. Defendants have failed to produce the requested records promptly.

COUNT IV - VIOLATION OF FOIA - JANUARY 15 REQUEST

34. The above paragraphs are incorporated herein.
35. Defendants are agencies subject to FOIA.
36. Plaintiff made a FOIA request to Defendants for agency records of Defendants.
37. Defendants have failed to provide a determination with regard to the request.
38. Defendants have failed to produce the requested records promptly.

WHEREFORE, Plaintiff asks the Court to:

- i. Order Defendants to conduct a reasonable search for records and to produce all non-exempt requested records;
- ii. Award Plaintiff attorney fees and costs; and
- iii. Enter any other relief the Court deems appropriate.

DATED: April 10, 2019

Respectfully Submitted,

/s/ Matthew Topic

Attorneys for Plaintiffs

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